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110TH CONGRESS
1ST SESSION

H. R. 2592

To amend the Federal Food, Drug, and Cosmetic Act to provide for one or more Critical Path Public-Private Partnerships to implement the Critical Path Initiative of the Food and Drug Administration, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JUNE 6, 2007

Ms. GIFFORDS (for herself, Mrs. BLACKBURN, and Mr. HALL of Texas) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to provide for one or more Critical Path Public-Private Partnerships to implement the Critical Path Initiative of the Food and Drug Administration, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Safe and Effective Drug Development Act of 2007''.

SEC. 2. PURPOSE.

The purpose of this Act is to provide for one or more Critical Path Public-Private Partnerships to accelerate the translation of new scientific discoveries into new medical products that will cure and better treat disease, improve health care, prolong longevity and wellness, reduce health care costs, and enhance American competitiveness in the 21st century.

SEC. 3. FINDINGS.

The Congress finds as follows:

(1) The Critical Path Initiative is the Food and Drug Administration's effort to stimulate and facilitate a national effort to modernize the process of innovation and commercialization through which fundamental scientific discoveries are transformed from ''proof of concept'' and development into breakthrough medical products, therapies, and cures.

(2) On March 16, 2004, the Food and Drug Administration released a report entitled ''Innovation/Stagnation: Challenge and Opportunity on the Critical Path to New Medical Products'', addressing the recent slowdown in innovative medical therapies submitted to the Food and Drug Administration for approval. The report describes the urgent need to modernize the medical product development proc-

ess—the Critical Path—to make product development more predictable and efficient.

(3) The Food and Drug Administration has committed to working with companies, patient groups, academic researchers, and other stakeholders to coordinate, develop, and disseminate solutions to scientific hurdles that are impairing the efficiency of product development across the life science industries. For example, the Food and Drug Administration has released a Critical Path Opportunities List of over 75 research priorities that, if accomplished, would modernize the drug development process by 2010 and would help to make new medical discoveries available to Americans faster and at a lower cost.

(4) The Food and Drug Administration has already initiated partnerships to share knowledge, streamline the cost and time of preclinical drug safety evaluation, and better inform the use of ''personalized medicine''.

(5) However, much more must be done to foster the collaborative culture that must exist to modernize the medical product development process. Collective sharing of scientific information and research methodology across the entire health care commu-

nity is crucial to igniting the medical innovation required to keep pace with biomedical research.

(6) The power of public-private partnerships is vital to accomplish these tasks and to ensure that new scientific discoveries—in fields such as genomics and proteomics, imaging, and bioinformatics—can be more rapidly and effectively applied to cure diseases, enhance treatments, improve health care, prolong longevity and wellness, reduce health care costs, and enhance American competitiveness in the 21st century.

SEC. 4. CRITICAL PATH PUBLIC-PRIVATE PARTNERSHIPS.

Subchapter E of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb et seq.) is amended by adding at the end the following:

"SEC. 566. CRITICAL PATH PUBLIC-PRIVATE PARTNERSHIPS.

''(a) ESTABLISHMENT.—The Secretary, acting through the Commissioner of Food and Drugs, shall enter into one or more collaborative agreements, to be known as Critical Path Public-Private Partnerships, with one or more eligible entities to implement the Critical Path Initiative of the Food and Drug Administration by developing innovative, collaborative projects in research, education, and outreach for the purpose of fostering medical product

innovation, enabling the acceleration of medical product development, and enhancing medical product safety.

''(b) ELIGIBLE ENTITY.—In this section, the term 'eligible entity' means an entity that meets each of the following:

''(1) The entity is—

''(A) an institution of higher education (as such term is defined in section 101 of the Higher Education Act of 1965); or

''(B) an organization described in section 501(c)(3) of the Internal Revenue Code of 1986 and exempt from tax under section 501(a) of such Code.

''(2) The entity has experienced personnel and clinical and other technical expertise in the biomedical sciences.

''(3) The entity demonstrates to the Secretary's satisfaction that the entity is capable of—

''(A) developing and critically evaluating tools, methods, and processes—

''(i) to increase efficiency, predictability, and productivity of medical product development; and

"(ii) to more accurately identify the benefits and risks of new and existing medical products;

"(B) establishing partnerships, consortia, and collaborations with health care practitioners and other providers of health care goods or services; pharmacists; pharmacy benefit managers and purchasers; health maintenance organizations and other managed health care organizations; health care insurers; government agencies; patients and consumers; manufacturers of prescription drugs, biological products, diagnostic technologies, and devices; and academic scientists; and

"(C) securing funding for the technical programs of a Critical Path Public-Private Partnership from Federal and nonfederal governmental sources, foundations, and private individuals.

"(c) FUNDING FROM CERTAIN INDIVIDUALS AND ORGANIZATIONS.—

"(1) PROHIBITION.—The Secretary may not enter into a collaborative agreement under subsection (a) unless the eligible entity involved provides an assurance that the entity will not accept any

funding for the technical programs of a Critical Path Public-Private Partnership from any individual or organization that manufactures, distributes, or sells any product that is regulated by the Food and Drug Administration.

''(2) WAIVER.—Paragraph (1) (and any assurance provided thereunder) does not prohibit an eligible entity from accepting funding from a consortium of companies whose products are regulated by the Food and Drug Administration if the Secretary—

''(A) determines that such acceptance would not result in any conflict of interest for the eligible entity, the Partnership, or the Government; and

''(B) issues a waiver allowing such acceptance.

''(d) ANNUAL REPORT.—Not later than 18 months after the date of the enactment of this section, and annually thereafter, the Secretary, in collaboration with the parties to each Critical Path Public-Private Partnership, shall submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives—

''(1) reviewing the operations and activities of the Partnerships in the previous year; and

''(2) addressing such other issues relating to this section as the Secretary determines to be appropriate.

''(e) DEFINITION.—In this section, the term 'medical product' includes a drug, a diagnostic test, a biological product, a device, and any innovative combination of such products.

''(f) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated $5,000,000 for fiscal year 2008 and such sums as may be necessary for each of fiscal years 2009 through 2012.''.

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